WOLFF SYSTEM TECHNOLOGY CORPORATION

Dockets Management Branch (HFA-305)
FOOD and DRUG ADMINISTRATION
5630 Fishers Lane, room 1061
Rockville, MD 20852

June 1, 1999

Re: ANPRM [Docket No. 98N-1170]

Dear Sir or Madam;

Thank you for the opportunity to participate in this important process. We at Wolff System support the FDA's efforts to enact good regulations that foster compliance and improve communications to the tanning public. We are all best served through responsible application of sunlamp products and informed decision-making on the part of the tanning public who should possess reliable available knowledge of the risks and benefits of exposure to UVR.

Your ANPRM raises a number of questions, and those will be tendered to FDA under separate cover through our other indoor tanning industry affiliations. Wolff System's expertise is largely drawn from low pressure fluorescent sunlamps and the sunlamp products that employ them, so I offer some observations for your consideration, primarily in this regard.

You indicate interest in harmonizing FDA standards with IEC 335-2-27. This may not be in the public's best interest. IEC regulates irradiance of sunlamps, but does not regulate exposure levels from the sunlamp product "system". Because of the variables in the way sunlamps are employed in systems, it seems more prudent to continue FDA's direction in speaking ultimately to exposure, not performance characteristics of individual system components.

Sunlamp technology is not changing as much as implied in your ANPRM comments. The low pressure technology remains largely unchanged since its inception. There are differing UV phosphor combinations offered from time to time, with the purpose of delivering different results to tanners. Most of these new products are aimed at the expressed desire of some tanners for shorter controlled tanning sessions (exposure schedules again, instead of lamp properties). There are also numerous marketing claims regarding new technology or technical advances, but from our viewpoint those claims are almost always traced to different blends of phosphors. Commercial claims instead of technology. Some technical advances have been achieved in the consistency of sunlamp performance and service life.

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In sunlamp product systems there are more technological changes. Lamp drivers (ballasts) are different, some optical systems are improving, changes in circuitry alter system performance and some new tanning systems employ larger numbers of lamps. Most of these changes are directed at satisfying those constituents desiring a shorter session in the controlled tanning process. A normal market response to a 'fast food' culture. This area is also best controlled through management of the exposure schedule for the specific sunlamp product for tanners with differing skin phototypes.

When considering revisions to the maximum timer interval, also consider that compliance follows a good regulation. Making no claims to medical competence, I observe regularly that the current exposure schedules developed for skin phototypes I and II are considered far more conservative than the reality of a population that is 80+% types III and higher. New timer intervals or exposure schedules, if implemented, should incorporate human sensitivity and tolerance to UVR as well as the tanner's absence of, or level of, an existing tan. We are evaluating a proposed method of phototyping / subtyping that takes these variables into consideration for purposes of determining an exposure schedule. If a new regulation 'makes sense' to its regulated parties, it will be more closely and voluntarily followed, thus yielding the maximum public benefit.

It is possible that warning labels on sunlamp products are not always read by tanning salon patrons. A factor is the length of the warning and the detail, as you assess. Another factor is familiarity with the equipment and its use... we don't consult the owner's manual or read the complete air bag warning each time we enter our car. I therefore believe that highlighting risks on the equipment label influences very few, while increased compliance with sound FDA regulations by the salon operator will influence the behavior of many. Consider posting information about the tanning equipment and the employed sunlamps at the entry to, or within, the tanning room, with referral to posted material on the equipment label. This material can be provided by the equipment and/or lamp maker, prepared in a way that is easily understood by the tanning patron.

While we agree with your intentions regarding modifications to sunlamp products as listed in II. 3. Revisions under consideration, we strongly recommend that FDA employ rigid standards to those pursuing re-certification of sunlamp products *unless they are primarily in the business of producing sunlamp products under FDA's close supervision.* In this way, FDA has greater assurance that the re-certifying is performed by firms with demonstrated competence, is well-known to its regulators, has adequate liability protection in the interest of the tanning patron and salon operator, and can do *all* of the things necessary to keep the sunlamp product in compliance. The re-certifier should not be allowed to make some modifications such as re-labeling and ignore others such as replacing the exposure timer and its redundant safeguards. The re-certifier must assure

that the re-certification does not void the testing agencies' (UL, ETL) listing, which if voided may violate the salon's agreement with its liability insurance carrier. Further, the original manufacturer's warranty must not be voided as that would exonerate the original manufacturer from its product liability responsibility to the tanning patron and salon operator.

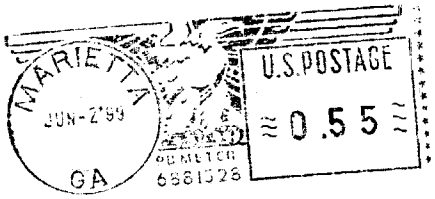
The principal consideration for standardizing sunlamps, as only one component of the sunlamp product system, should be the protection of the public health. A secondary concern may be making oversight easier for those charged with the oversight. While we agree that some industry and state regulators may find the administration of compliant sunlamp use cumbersome, the objective of current 'compatibility' regulations is good: to assure that tanners are only exposed to UVR at approved levels. Some extra study to do this well is a good thing. It is possible that the Ultraviolet Index scale will provide a universal rating method for both sunlamp products and sunlamps. We support an effort, already underway within the industry, to answer this question.

More importantly on sunlamp performance, a standard testing and evaluation method is desirable. Current compatibility regulations require the photobiological effects of one lamp to be similar within 10% of another for the lamps to be substantially equivalent. Without factoring for manufacturing tolerances present in all fluorescent lamps, this allows variance of 20% from extremes of the range. Additionally, not all lamp manufacturers test lamps in the same way, or even at the same point in the lamp life. Ultraviolet-producing phosphors degrade from 5 to 25% in the first 100 hours of operation, depending upon phosphor selection and other design decisions and process factors in the manufacture of the lamp. Where a company selects 100 hours instead of the first hour for their lamp measurement, actual exposure early in the lamp's life can be 25% higher than expected for the tanner. Sunlamps are not 'aged' before use in the salon, they are employed from '0' hours. Any new lamp standards should require lamps in a grade/class be substantially equivalent initially and at some later point, say 50 or 100 hours, under a standard testing method, with the resulting data made readily available to industry regulators in a standard form that is complete and easy to understand.

Respectfully submitted,

Michael Stepp
President
Wolff System Technology Corp.

cc: W. Howard Cyr, Ph.D.



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